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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,304	09/24/2003	Bronislava Gedulin	0101US-UTL1	8486

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Intellectual Property Department
Amylin Pharmaceuticals, Inc.
9360 Towne Centre Drive
San Diego, CA 92121

EXAMINER	
WINSTON, RANDALL O	

ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
01/31/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@amylin.com
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Office Action Summary	Application No.	Applicant(s)	
	10/671,304	GEDULIN ET AL.	
	Examiner	Art Unit	
	Randall Winston	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,9,27,29,31 and 33-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,9,27,29,31, and 33-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of receipt and entry of them amendment filed on 11/19/2010.

Claims 1, 6, 9, 27, 29, 31 and new claims 33-40 have been examined on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6, 9, 27, 29, 31 and 33-40 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al. (US 5,677,279) in further view of Iovanna et al. (US 5436169), Valter (Derwent Acc 1979-G6671B and/or SU 628925A, see abstract), Sachs et al. (US 20010018049), Jorgensen et al. (US 4,370,317), and Haddad et al. (*The use of a low fat diet in the treatment of acute pancreatitis*, American Journal of Gastroenterology, (September 2000), Vol. 95, No. 9, pp. 2479)

Applicant claims a method of reducing or inhibiting the level of enzymatic activity or enzymatic secretion in pancreatic cells in a mammalian subject (i.e. human) wherein the subject is afflicted with acute and/or chronic pancreatitis comprising administering to said subject an effective amount of the amylin analog of 25,28,29 Pro-h-amylin and/or amylin, an analgesic and a pancreatic enzyme and/or a regimen (i.e. a low fat diet).

Young teaches a method of relieving the pain and/or treating painful inflammation disorders in a mammalian subject comprising administering to said subject an effective amount of the same amylin analog as the claimed invention amylin analog of 25,28,29 Pro-h-amylin and/or same amylin in combination with an analgesic to treat painful inflammation disorders (see, e.g. see abstract, claims and claims 18-19 and column 4 lines 63-64). Young, however, does not teach that the mammalian subject's pain is caused by painful inflammation disorders such as acute and/or chronic pancreatitis nor Young teach the claimed pancreatic enzyme included within the composition and/or to include within the treatment of acute and/or chronic pancreatitis a low fat diet.

Iovanna et al. beneficially teaches that acute pancreatitis is a very painful inflammation condition and/or inflammation disorder (see, e.g. entire patent including abstract).

Valter beneficially teaches that acute pancreatitis is a very painful inflammation condition and/or inflammation disorder (see, e.g. abstract).

Sachs beneficially teaches that acute pancreatitis and chronic pancreatitis are very painful inflammation conditions and/or inflammation disorders (see, entire document e.g. paragraph 0002).

Jorgensen et al. beneficially teach that pancreatin treats pancreatitis (please note that pancreatin is defined as an extract from the pancreas of animals that contains pancreatic enzymes) (see, e.g. column 8 lines 36-41).

Haddad et al. benefically teach to include within the treatment of acute pancreatitis a low fat diet (see, e.g. entire article).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have administered the same amylin analog as the claimed invention's amylin analog of 25,28,29 Pro-h-amylin and/or the same claimed amylin and an analgesic to treat the painful inflammation disorder of acute and/or chronic pancreatitis in a mammalian subject because Young teaches that the amylin analog of 25,28,29 Pro-h-amylin and/or amylin and an analgesic treats painful inflammation disorders and Iovanna and/or Valter and/or Sachs teaches that acute pancreatitis and/or chronic pancreatitis are painful inflammation disorders. Moreover, please note that the instantly claimed *in vivo* underlining functional effect (i.e. reducing or inhibiting the level of enzymatic activity or enzymatic secretion in pancreatic cells in a mammalian subject) would be intrinsic upon such administration of the same claimed amylin analog composition to a mammalian subject when treating the painful inflammation disorder of acute and/or chronic pancreatitis. Furthermore, the claimed amylin analog composition would also intrinsically treat the broadly genus claimed pancreatitis disorder because acute pancreatitis and/or chronic pancreatitis are forms and/or species of pancreatitis. In addition, it would have been obvious to modify Young's administration's method of administering the same amylin analog as the claimed inventions amylin analog of 25,28,29 Pro-h-amylin and/or same amylin in combination with an analgesic to include the teaching of Jorgensen which states a pancreatic enzyme such as pancreatin is well known in the art for treating pancreatitis and/or to include the teachings of Haddad which discloses to include within the treatment of acute pancreatitis a low fat diet because the above combined teachings as

a whole would create the claimed method of treating the painful inflammation disorder of acute pancreatitis in a mammalian subject. The adjustments of other conventional working conditions (i.e. the substitution of the administration of one mammalian subject for another and determining suitable amounts/ranges of each active ingredient within the claimed composition), is deemed a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Applicant's arguments have been carefully considered but they are not deemed persuasive. Applicant argues Iovanna and/or Valter are cited by the Examiner for teaching that acute pancreatitis is a painful inflammation disorder, but both references are also completely silent regarding enzymatic activity or enzymatic secretion in pancreatic cells. Examiner, however, maintains his rejection because the instantly claimed *in vivo* underlining functional effect (i.e. reducing or inhibiting the level of enzymatic activity or enzymatic secretion in pancreatic cells in a mammalian subject) would be intrinsic upon such administration of the same claimed amylin analog composition to a mammalian subject when treating the painful inflammation disorder of acute and/or chronic pancreatitis. Therefore, for the reasons fully set forth above under USC 103, the above cited references of Young, Iovanna, Valter, Sachs, Jorgensen and Haddad, as a whole, reasonably suggest that the claimed amylin analog and/or the claimed amylin can be used to treat pancreatitis in a mammalian subject afflicted with pancreatitis and/or its pancreatitis's claimed species.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RW

/Christopher R. Tate/
Primary Examiner, Art Unit 1655